

**Policy and Procedure**

<b>PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCOTH018.1025</b>	<b>MISCELLANEOUS PRODUCTS ORAL RINSES</b> See <a href="#">Appendix A</a> for medications covered by policy
<b>Effective Date: 1/1/2026</b>	<b>Review/Revised Date:</b> 01/17, 07/17, 07/18, 07/19, 09/19, 08/20, 09/21, 09/22, 08/23, 08/24, 09/25 (JEF)
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<b>Approved by: Oregon Region Pharmacy and Therapeutics Committee</b>	

**SCOPE:**

Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

Commercial  
Medicaid

**POLICY CRITERIA:**

**COVERED USES:**

Must be in accordance with use authorized by the FDA. Covered uses are limited to:

- Mucositis/stomatitis secondary to chemotherapy or radiation
- Xerostomia secondary to chemotherapy or radiation
- Sjögren’s syndrome

Coverage for Medicaid is limited to a condition that has been designated a covered line-item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children and adolescents up to their 21st birthday who are enrolled in Medicaid. Management of unfunded conditions falls under this benefit when they impact the ability to grow, develop or participate in school and the applicable indication-specific criteria below are met.

**REQUIRED MEDICAL INFORMATION:**

**For mucositis/stomatitis secondary to chemotherapy or radiation**

1. Diagnosis of mucositis/stomatitis secondary to chemotherapy or radiation

**AND**

2. Documented trial of TWO of the following:
  - a. Over-the-counter oral anesthetics (such as OraGel®, Anbesol®)
  - b. Prescription oral anesthetics (such as viscous lidocaine 2%)
  - c. Saliva substitutes (such as Biotene®, Mouth Kote®)

**PHARMACY PRIOR AUTHORIZATION  
POLICY AND CRITERIA  
ORPTCOTH018**

**MISCELLANEOUS PRODUCTS**

**ORAL RINSES**

See [Appendix A](#) for medications covered by policy

- d. Magic mouthwash - a compounded product often containing viscous lidocaine, Maalox®, and diphenhydramine. Multiple formulations are compounded and these may contain different ingredients. Note: premeasured kits for these solutions are not available on formulary
3. For Aquoral®, Mugard®: Trial and failure, intolerance, or contraindication to Gelclair®

Reauthorization requires:

1. Documentation of continued need for therapy (such as continued chemotherapy and/or radiation)
2. Documentation of initial response to therapy (such as reduced signs and symptoms of mucositis, increased ability to tolerate food and beverages)

**For xerostomia secondary to chemotherapy or radiation and Sjögren's syndrome**

1. Diagnosis of one of the following: xerostomia secondary to chemotherapy, xerostomia secondary to radiation, or Sjögren's syndrome

**AND**

2. Documented trial to both of the following:
  - a. TWO over the counter saliva substitutes (such as Biotene®, Mouth Kote®)
  - b. Saliva stimulants (such as sugar free lozenges or chewing gum)

Reauthorization requires:

1. Documentation of continued need for therapy (such as continued chemotherapy and/or radiation)
2. Documentation of initial response to therapy (such as reduced signs and symptoms of xerostomia, increased ability to tolerate food and beverages)

**EXCLUSION CRITERIA:** N/A

**AGE RESTRICTIONS:** N/A

**PRESCRIBER RESTRICTIONS:** N/A

**COVERAGE DURATION:**

1. For mucositis/stomatitis and xerostomia secondary to chemotherapy or radiation initial authorization and reauthorization will be approved for six months.
2. For Sjögren's syndrome initial authorization and reauthorization may be reviewed annually to assess continued medical necessity and effectiveness of medication.

**QUANTITY LIMIT:**

Gelclair®: Three single-use packets (45 mL) per day

**PHARMACY PRIOR AUTHORIZATION  
POLICY AND CRITERIA  
ORPTCOTH018**

**MISCELLANEOUS PRODUCTS**

**ORAL RINSES**

See [Appendix A](#) for medications covered by policy

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*Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.*

*Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.*

*Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.*

*Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.*

**INTRODUCTION:**

The products on this policy are classified as medical devices, and therefore, do not have an active drug ingredient. These products have differing ingredients that produce a protective layer over the oral cavity. The products claim to form a barrier that can reduce pain and enable patients to eat and drink more easily. These products require a written prescription for dispensing.

**FDA APPROVED INDICATIONS:**

These products are approved by the FDA as medical devices and do not have approval as drug products.

- Aquoral®: Intended to provide relief from chronic and temporary xerostomia (dry mouth) which may be a result of disease such as Sjogren's, oral inflammation, medication, chemo or radiotherapy, stress, or aging. Aquoral® relieves symptoms of dry mouth such as difficulties in swallowing, speech, and changes in taste.
- Gelclair®: Indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.
- Mugard®: Indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

**PHARMACY PRIOR AUTHORIZATION  
POLICY AND CRITERIA  
ORPTCOTH018**

**MISCELLANEOUS PRODUCTS**

**ORAL RINSES**

See [Appendix A](#) for medications covered by policy

**POSITION STATEMENT:**

There is limited clinical evidence supporting the use of these types of products and no evidence to support the use of these agents over other standard of care regimens.

These products are approved medical devices. If approved, they may be processed at a pharmacy for the appropriate medical benefit cost-share and will apply to medical expenses.

*European Society for Medical Oncology (ESMO) Clinical Practice Guidelines for diagnosis, treatment, and follow-up for oral and gastrointestinal mucositis*

Oral mucositis is a common complication of head and neck radiation and high-dose chemotherapy (for example, 5-FU, irinotecan, capecitabine). The pain severity can lead to requirement of enteral nutrition support as well as escalated doses of opioid analgesics. In addition, some of the newer oncology agents, such as tyrosine kinase inhibitors (TKIs) and mTOR inhibitors, have led to oral and gastrointestinal mucositis despite their targeted approach to therapy.

Prevention is a key component to reducing the severity of mucositis side effects. These include reducing the sources of trauma (ill-fitting prostheses), eliminating extreme temperature foods/beverages, proper oral hygiene, and regular checking of the oral mucosa. Oral rinses (alcohol-free) are recommended to be used at least four times a day for about one minute each time, after brushing teeth. Due to conflicting evidence, there is not a recommended oral rinse and the ESMO guidelines state that plain water can be used, although they prefer saline rinses for target therapies (for example, TKIs and mTOR inhibitors).

For the treatment of oral mucositis, the guidelines focus on preventing infection with various antibacterial rinses. These guidelines do not mention the products outlined on this policy.

Additional organizations providing guidance on oral mucositis in cancer patients including the Multinational Association of Supportive Care in Cancer/ International Society of Oral Oncology (MASCC/ISOO) and National Comprehensive Cancer Network (NCCN) do not provide recommendations in regards to these agents due to lack of quality evidence.

The Sjögren's Foundation Clinical practice guidelines for oral management of Sjögren disease: Dental caries prevention, recommend increasing saliva through gustatory, masticatory and pharmaceutical agents. Recommended pharmaceutical agents are saliva stimulants such as sugar free lozenges or chewing gum;

**PHARMACY PRIOR AUTHORIZATION  
POLICY AND CRITERIA  
ORPTCOTH018**

**MISCELLANEOUS PRODUCTS**

**ORAL RINSES**

See [Appendix A](#) for medications covered by policy

pilocarpine; and cevimeline. The guidelines do not give any recommendations around saliva substitutes. The European League Against Rheumatism (EULAR) provides recommendations for treatment of oral dryness based upon severity of gland dysfunction. Saliva substitutes are only recommended for severe dysfunction and non-responders to other treatment options.

**REFERENCE/RESOURCES:**

1. Peterson DE, Boers-Doets CB, Bensadoun RJ et al. Management of oral and gastrointestinal mucosal injury: ESMO Clinical Practice Guidelines for diagnosis, treatment, and follow-up. *Ann Oncol*. 2015; 26 (suppl 5): v139-v151.
2. Yarom N, Hovan A, Bossi P, et al. Systematic review of natural and miscellaneous agents for the management of oral mucositis in cancer patients and clinical practice guidelines-part 1: vitamins, minerals, and nutritional supplements. *Support Care Cancer*. 2019;27(10):3997-4010. Available from: <https://pubmed.ncbi.nlm.nih.gov/31286229/>. Accessed Sept 9, 2021.
3. Saunders DP, Epstein JB, Elad S, et al. Systematic review of antimicrobials, mucosal coating agents, anesthetics, and analgesics for the management of oral mucositis in cancer patients. *Support Care Cancer*. 2013;21(11):3191-3207. Available from: <https://pubmed.ncbi.nlm.nih.gov/23832272/>. Accessed Sept 9, 2021.
4. Bensinger W, Schubert M, Ang KK *et al*. NCCN task force report: prevention and management of mucositis in cancer care. *J Natl Compr Canc Netw*. 2008; 6 Suppl 1:S1.
5. Zero DT, Brennan MT, Daniels TE, *et al*. Clinical practice guidelines for oral management of sjögren disease: dental caries prevention. *J Am Dent Assoc* 2016;147:295–305. Available from: <https://pubmed.ncbi.nlm.nih.gov/26762707/>. Accessed Sept 9, 2021.
6. Ramos-Casals M, Brito-Zerón P, Bombardieri S On behalf of the EULAR-Sjögren Syndrome Task Force Group, *et al*. EULAR recommendations for the management of Sjögren's syndrome with topical and systemic therapies. *Annals of the Rheumatic Diseases*. 2020;79:3-18.
7. Fortovia Therapeutics, Inc. GelClair. Available at <http://www.gelclair.com> (Accessed Sept 9, 2021)
8. EUSA Pharma. Caphosol. Available at <https://eusapharma.com/our-focus/our-products> (Accessed Sept 9, 2021)
9. OraPharma. Neutrasal. Available at <http://www.neutrasal.com/> (Accessed Sept 9, 2021)
10. U.S. Food & Drug Administration 510(k) Premarket Notification database. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> (Accessed Sept 18, 2023).

**PHARMACY PRIOR AUTHORIZATION  
POLICY AND CRITERIA  
ORPTCOTH018**

**MISCELLANEOUS PRODUCTS**

**ORAL RINSES**

See [Appendix A](#) for medications covered by policy

**APPENDIX A:**

<b>CODING</b>		
<b>Brand Name</b>	<b>Generic Name</b>	<b>Procedure Code</b>
<b>Aquoral<sup>®</sup></b>	Artificial saliva	A9155
<b>Gelclair<sup>®</sup></b>	potassium sorbate/ hydroxyethylcellulose/sodium hyaluronate	J3490
<b>Mugard<sup>®</sup></b>	Oral mucoadhesive	A9156